Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):
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[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being transmitted via the Patent and Trademark Office electronic filing system on the date noted below.
Dated: March 12, 2009 Name of Person Certifying: Olimpia Jakubowska Wrobel Printed Name: Olimpia Jakubowska-Wrobel

Docket No. ECV-5783

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Marquez, et al.	Group Art Unit: 3738
Application No.: 10/811,565	Examiner: Christopher D. Prone
Filing Date: March 29, 2004	**Customer Number: 30452**
For: CONTROLLED SEPARATION HEART VALVE FRAME	Confirmation No.: 1380

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Dear Sir:

This is an appeal from the final rejections of claims 1-18. For the reasons discussed below, Applicants request reversal of the rejection and allowance of the claims.

FEES

The Notice of Appeal along with a Pre-Appeal Brief Request for Review were filed on June 27, 2008, a response to which was dated January 14, 2009, making this Appeal Brief timely with a one month extension fee. **Accordingly, Applicants Petition for a one (1) month extension fee pursuant to 37 CFR §1.136(a)(1) to extend the period of response to on or before March 14, 2009.**

The extension fee of $130 under 37 CFR §1.17(a)(1) should be charged to Deposit Account No. 50-1225 (ECV-5783).

The Commissioner is hereby authorized to charge the Appeal fee of $540 under 37 C.F.R. §§41.20(b)(2) to Deposit Account No. 50-1225 (ECV-5783).

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

The following comply with the subparts of 37 CFR §41.37(c)(1):

i.

REAL PARTY IN INTEREST

The real party in interest is Edwards Lifesciences Corporation of Irvine, California.

ii.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

iii.

STATUS OF THE CLAIMS

Claims 1-18 are pending and appear in the attached claims appendix. Claims 19-23 are canceled. Claims 1-18 stand rejected, and Applicants appeal herein for their allowance.

iv.

STATUS OF AMENDMENTS

The Amendment After Final filed February 12, 2008 was not entered as indicated on the Advisory Action dated April 2, 2008.

v.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention generally relates to a highly flexible internal leaflet support frame for a prosthetic heart valve designed to separate into individual cusps after implantation. The leaflet

support frame (or "stent" or "wireform") has a plurality of alternating cusps on an inflow end and commissures on an outflow end. The cusps of flexible leaflets attach around the support frame cusps. The support frame provides structural rigidity during implantation, but each support frame commissure has a point of weakness that is designed to fracture upon repeated relative movement of the cusps after implantation such that the support frame cusps separate. Because of the flexible nature of the heart valve, after the cusps separate the implanted heart valve does not significantly impede the natural motion of the annulus or adjacent vessel walls. The support frame may be a homogeneous material such as Nitinol with the point of weakness being a narrowing at the commissure tips. The commissure tips can include enlarged regions adjacent the point of weakness that help prevent the separated ends from poking through surrounding fabric.

Claim 1 recites a support frame for a flexible leaflet prosthetic heart valve including a plurality of cusps each sized and shaped to support a cusp of a flexible leaflet of the heart valve. The support frame also has a plurality of commissures, one each between each adjacent pair of cusps, the commissures each having a point of weakness designed to fracture upon repeated relative movement of the cusps after implantation such that the cusps move substantially independently of each other, wherein the support frame exhibits a substantially continuous stiffness along the cusps and commissures similar to that resulting from the cusps and commissures being formed integrally. Exemplary support for claim 1 can be found in Figures 2-3, and in paragraphs [0028]-[0033]. Claim elements such as the support frame 40, commissures 44a, 44b, 44c, arcuate cusps 48a, 48b, 48c, and points of weakness 76, can be seen in Figures 2 and 2A. Support for the term "substantially continuous stiffness" is found in paragraph [0032], and in other places.

Claim 11 recites a support frame for a flexible leaflet prosthetic heart valve including a plurality of cusps sized and shaped to support cusps of flexible leaflets of the heart valve. The support frame also has a plurality of commissures, one each between each adjacent pair of cusps, the commissures and cusps being formed integrally of a homogeneous material and the commissures each having a point of weakness designed to fracture upon repeated relative movement of the cusps after implantation whereby the cusps can move substantially independently

of each other. Exemplary support for claim 11 can be found in Figures 2-3, and in paragraphs [0028]-[0033]. Claim elements such as the support frame 40, commissures 44a, 44b, 44c, arcuate cusps 48a, 48b, 48c, and points of weakness 76, can be seen in Figures 2 and 2A. Support for the term "formed integrally of a homogeneous material" is found in paragraph [0028], and in other places.

vi.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-18 are not patentable under 35 U.S.C §103(a), as being obvious over U.S. Patent No. 6,736,845 to Marquez, et al. in combination with U.S. Patent No. 6,696,169 (equivalent of WO 00/53356 to Klöckner, et al.).

vii.

ARGUMENT

Whether claims 1-18 are obvious over Marquez, et al. in combination with Klöckner, et al.

Applicants respectfully disagree with the rejection and request reconsideration.

Marquez, et al. disclose a stent assembly described, in pertinent part, as seen at col. 10, lines 6-43,:

> The final component of the stent assembly 46 is an attachment means 90 for joining each of a cloth-covered stent members 74. Preferably, the attachment means 90 comprises threads or sutures sewn through the central holes in each of the circular tips 80, as shown in FIG. 5, although other suitable attachment means could be used, such as rings, cinches, or the like. The attachment means 90 may be wrapped around or sewn through the cloth cover 72. In joining the tips 80, the attachment means 90 are desirably not wrapped extremely tightly, but are instead provided with some slack to permit relative movement of the tips, as will be described below. When the stent members 74 are attached, as seen in FIG. 5, the stent 70 exhibits three cusps corresponding to the cusp region 76 of each member, and three upstanding commissures defined by the juxtaposition of adjacent pairs of commissure regions 78.
>
> ...
>
> In a preferred embodiment of the present invention the attachment means 90 comprises a non-bioresorbable material to ensure that the individual stent members 74 are maintained in the shape of the stent 70. In an alternative configuration, however, the attachment

> means 90 comprises a bioresorbable material that dissolves over a period of time after implantation.... As a consequence, each individual stent member 74 and associated leaflet 72 moves entirely independently of the others, albeit all oscillating with the natural contractions and expansions of the surrounding aortic wall. Such independent leaflet movement may greatly reduce any potential pressure drop across the valve.

Marquez, et al. does not disclose the presently claimed support frame (stent) having a substantially continuous stiffness along the cusps and commissures and designed to fracture upon repeated relative movement of the cusps after implantation.

Marquez, et al. instead discloses ***flexible*** commissures that permit the separate cusps to pivot with respect to one another. This is not a substantially continuous stiffness. In one embodiment, the commissures may be bioresorbable so as to dissolve over a period of time after implantation and permit each individual stent member 74 and associated leaflet 72 to move entirely independently of the others. The specific embodiment cited by the Examiner shows sutures 90 which connect the separate stent members 74 and may or may not be bioresorbable. Note the passage above which states that "In joining the tips 80, the attachment means 90 are desirably not wrapped extremely tightly, but are instead provided with some slack to permit relative movement of the tips, ..." That is, the sutures permit significant relative cusp movement even prior to implant and dissolution.

Claim 1 specifies a support frame that exhibits a substantially continuous stiffness along the cusps and commissures similar to that resulting from the cusps and commissures being formed integrally. The support member commissures are designed to fracture upon repeated relative movement of the cusps after implantation.

Examiner Prone mis-characterizes Marquez, et al. as having "a plurality of ear shaped commissures 60 further comprising a fragile bridge 90..." The "bridge" is not fragile, instead the "bridge" is highly flexible. The various "attachment means 90" of Marquez, et al. include sutures, rings, etc. that *hold circular tips 80 together* with some slack to permit relative movement. In one version, the attachment means 90 are bioresorbable, which is the only variant that separates after implant. Even the bioresorbable embodiment starts off as being highly flexible. The intent in all of the embodiments is to provide flexibility between the cusps *without fracture*, and in one case

to enable gradual resorption. Designing the commissures to fracture would be counter to the intent of the invention of Marquez, et al. Moreover, none of the attachment means 90 of Marquez, et al. renders the support frame substantially continuously stiff along its cusps and commissures similar to that resulting from the cusps and commissures being formed integrally. If that were the case, the goal of great flexibility between the cusps would be thwarted.

With respect to claim 11, Examiner Prone states that Marquez, et al. does not disclose a support frame of a continuous homogeneous material. However, note the embodiment of Fig. 22 which is a one piece stent having coil spring tips 334. This configuration further illustrates the difference between the present invention and the various embodiments of Marquez, et al. The former involves commissures having a point of weakness designed to fracture upon repeated relative movement of the cusps after implantation, while the latter exhibits highly flexible commissures that are not designed to fracture but instead to provide pivot points for the stent cusps.

The Examiner relies on Klöckner, et al. to contribute to Marquez, et al. "a continuous homogeneous metal sheet [made] with dedicated thinner weak portions as break points in the same field of endeavor for the purpose of ease of production." Thus, the Examiner deduces, it would have been obvious "to combine the teaching of continuous homogeneous breakable connections as taught by [Klöckner] with the implant of Marquez in order to simplify production and reduce costs."

Applicants note that the publication to Klöckner, et al. pertains to an expanded metal mesh cut so that certain links remain joined at nodes configured as break points. The resulting expanded metal mesh can be handled and worked just as easily as normal expanded metal mesh. And, at the paragraph bridging cols. 1 and 2:

> The mesh can be filled out or coated with curing or elastomeric polymerizing or dry substances or compounds and thus are useful e.g. as lathing as well as in roofing applications as products having become popular as "lead replacements". Further possible applications include: 1. spacers for cavity claddings, 2. tailored packings for spherical objects and the like, 3. drying grids and filter cages for industrial and domestic purposes, 4. mattings as employed in automotive repair as a replacement for glass-fiber plastics.

First, Applicants contest the statement by the Examiner that this is "in the same field of endeavor" as heart valve fabrication. In the Advisory Action, the Examiner broadens the field of endeavor to be "structural fabrication of metal devices." This is overbroad. The natural consequence of such a broad field is that any metal-working technique may be imputed to an existing heart valve to render obvious a novel construction in that specialized field, which is what we have here. Applicants do not believe that such a broad collection of prior art is warranted.

Applicants fail to see how a metal mesh product for industrial uses informs one of skill in the art of designing heart valves. There is no motivation given by the Examiner for borrowing the disclosure of Klöckner, et al. other than generalized and entirely abstract benefit of simplifying production and reducing costs. How is the production of single heart valve support frames simplified, and how are costs reduced, by incorporating a manufacturing process for a large sheet metal mesh with numerous nodular break points? As described in col. 3 at the beginning of the Detailed Description of Klöckner, et al., the metal mesh is "conventionally produced" using top and bottom blades. This process is far removed from the much more careful and exacting formation of heart valve stents.

Perhaps more importantly, Examiner Prone fails to explain why one of skill in the art (without hindsight) would wish to provide commissures that fracture upon repeated relative movement of the cusps after implantation. To borrow from Klöckner, et al., or any other disclosure of frangible metal connections, requires some motivation. Applicants assert that there has been no prime *facie case* made out sufficient to suggest to one of skill in the art to combine the references.

Accordingly, Claims 1-18 are allowable over the combination of Marquez, et al. and Klöckner, et al.

Examiner Prone also cites several other old patents that teach breakable metal joints. USPN 658,598 pertains to a spectacle manufacturing technique, USPN 2,247,499 pertains to a screw manufacturing technique, and USPN pertains to a pool ball manufacturing technique. The existence of frangible connections in various unrelated fields provides one of skill in the art with no greater insight prior to the present invention for forming the claimed heart valve support stent.

Applicants respectfully find these references, as with Klöckner, et al., to be irrelevant.

viii.

CLAIMS APPENDIX

Claims 1-18 currently pending are attached hereto as an appendix.

ix.

EVIDENCE APPENDIX

None.

x.

RELATED PROCEEDINGS APPENDIX

None.

Respectfully submitted,

Date: March 12, 2009

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Claims Appendix

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of claims:

1. (Previously presented) A support frame for a flexible leaflet prosthetic heart valve, comprising:

a plurality of cusps each sized and shaped to support a cusp of a flexible leaflet of the heart valve; and

a plurality of commissures, one each between each adjacent pair of cusps, the commissures each having a point of weakness designed to fracture upon repeated relative movement of the cusps after implantation such that the cusps move substantially independently of each other, wherein the support frame exhibits a substantially continuous stiffness along the cusps and commissures similar to that resulting from the cusps and commissures being formed integrally.

2. (Original) The support frame of claim 1, wherein the support frame is a single, continuous, element.

3. (Original) The support frame of claim 2, wherein the support frame is formed from a continuous, homogeneous material.

4. (Original) The support frame of claim 3, wherein the commissures and cusps have substantially the same material stiffness in bending prior to reaching the point of fatigue.

5. (Original) The support frame of claim 1, wherein the support frame is made of Nitinol.

6. (Original) The support frame of claim 1, wherein each cusp of the support frame transitions into two commissure regions, and wherein the point of weakness at the commissures comprises a frangible bridge between adjacent commissure regions.

7. (Original) The support frame of claim 6, wherein the frangible bridge comprises a narrow portion of the support frame relative to adjacent portions.

8. (Original) The support frame of claim 6, wherein the point of weakness comprises a notch.

9. (Original) The support frame of claim 6, wherein the commissure regions terminate in enlarged ears on either side of the frangible bridge.

10. (Original) The support frame of claim 9, further including a biocompatible fabric covering the support frame, and wherein the enlarged ears are sized to prevent the commissure regions from poking through the fabric once the frangible bridge has fractured.

11. (Original) A support frame for a flexible leaflet prosthetic heart valve, comprising:

a plurality of cusps sized and shaped to support cusps of flexible leaflets of the heart valve; and

a plurality of commissures, one each between each adjacent pair of cusps, the commissures and cusps being formed integrally of a homogeneous material and the commissures each having a point of weakness designed to fracture upon repeated relative movement of the cusps after implantation whereby the cusps can move substantially independently of each other.

12. (Previously presented) The support frame of claim 11, wherein the support frame comprises three cusps and three commissures.

13. (Original) The support frame of claim 11, wherein the support frame is made of Nitinol.

14. (Original) The support frame of claim 11, wherein each cusp transitions into two commissure regions, and wherein the point of weakness at the commissures comprises a frangible bridge between adjacent commissure regions.

15. (Original) The support frame of claim 14, wherein the frangible bridge comprises a narrow portion of the support frame relative to adjacent portions.

16. (Original) The support frame of claim 14, wherein the point of weakness comprises a notch.

17. (Original) The support frame of claim 14, wherein the commissure regions terminate in enlarged ears on either side of the frangible bridge.

18. (Original) The support frame of claim 17, further including a biocompatible fabric covering the support frame, and wherein the enlarged ears are sized to prevent the commissure regions from poking through the fabric once the frangible bridge has fractured.

19-23. (Canceled)